

# Medicare Part D and Its Impact in the Nursing Home Sector: An Update

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*A study conducted by staff from Harvard Medical School  
for the Medicare Payment Advisory Commission*

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## **Medicare Part D and Its Impact in the Nursing Home Sector: An Update**

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### **Abstract**

In 2006, the Medicare Payment Advisory Commission (MedPAC) contracted with Harvard Medical School to explore how Medicare Part D's introduction changed the operations of long-term care pharmacies (LTCPs) and nursing homes, as well as implications of those changes for nursing home residents. Based on interviews conducted across a broad range of stakeholders (nursing homes, LTCPs, Part D plans, financial analysts covering the LTCP sector, consultant pharmacists, physicians working in nursing homes, and advocates for nursing home residents), the June 2007 report offered a snapshot of this sector's transition to Part D. In 2009, MedPAC contracted with Harvard Medical School to update this work by conducting a second round of stakeholder interviews, the findings of which are detailed in this report. The report briefly updates changes in the LTCP industry since early 2007 and describes the recent impact of Part D focusing on: Part D plan assignment and selection; PDP formularies and drug coverage; mechanics of dispensing medications to nursing home residents under Part D; and the impact of Part D on drug utilization and health outcomes for nursing home residents.

Since our initial report, stakeholders of all types have gained experience working through issues related to Part D coverage for nursing home residents. In the context of this increased experience and related safeguards adopted by CMS, many of the initial implementation challenges that arose during the transition to Part D have lessened over time. Overall, it seems providers have adapted to the new benefit and learned to work around its limitations. Formulary

coverage is generally viewed as adequate for meeting the needs of residents in most cases. Stakeholders have not perceived a change in overall drug utilization nor any adverse impact on resident outcomes, although they agreed that empirical analyses are needed to assess the impact of Part D on health, functioning, and quality of care. Nonetheless, stakeholders continued to describe the Part D program, particularly its reliance on private plans to administer the benefit and its emphasis on consumer choice, as a poor fit for the nursing home setting.

Stakeholders identified challenges in several areas, including:

*Residents' choice of plan and annual reassignments when plans lose benchmark status.*

Annual reassignment of dually eligible beneficiaries when their plans lose benchmark status for the upcoming year can result in significant clinical disruption as well as administrative burden for residents, nursing homes, and long-term care pharmacies. CMS has taken important steps to lessen these disruptions and allow time for changes in medication regimens to be made, but multiple stakeholders of different types described the “churning” of residents across plans from year to year as the biggest challenge associated with Part D at this time.

*PDP formulary adequacy and utilization management.* Formulary coverage generally was viewed as adequate for meeting the needs of nursing home residents, although stakeholders noted what they consider to be important exceptions. Moreover, several stakeholders noted that utilization management requirements such as prior authorization, step therapy, and quantity limits had increased over the past few years, a trend that is consistent with previous MedPAC-supported research on Part D formularies generally. CMS-instituted safeguards have reportedly helped lessen potential disruption to residents; however, important limitations to these safeguards were expressed (e.g., PDPs may cover a limited prescription fill rather than a 31 day supply if physicians initially fill a shorter duration prescription for clinical reasons). Nursing home

stakeholders also pointed to what they perceived to be continuing discrepancies in the information needed to satisfy utilization management requirements across plans and requested greater standardization in these policies.

*Financial implications of non-covered medications and withheld co-payments.* Due to regulatory requirements for timely medication dispensing for nursing home residents, LTCs often must dispense medications before payment is assured. Because nursing homes are required to provide all medications in a resident's care plan regardless of coverage, nursing homes and/or the LTCs with which they contract must absorb the costs of uncovered medications. Nursing home stakeholders reported that these costs are considerably higher than they were prior to Part D and that they have continued to increase over time. Although stakeholders generally noted some improvement since CMS adopted the "Best Available Evidence" (BAE) guidance, nursing home providers, LTCs, and consultant pharmacists reported continuing concerns about the process for identifying dual-eligible nursing home residents and difficulties in securing payment for copayments withheld before dual eligibility is recognized by the PDP.

*Ongoing communication challenges between PDPs, pharmacies, physicians, and NHs.* Communication between nursing homes, physicians, pharmacies, and PDPs around nursing home prescribing remains tenuous in the context of Part D. A complicating factor mentioned by LTC and nursing home stakeholders is that they often are not included by the PDP in key communications about plan assignment and coverage decisions for residents (e.g., around the need for some residents to select a new benchmark plan or the resolution status of prior authorization or other utilization management policies).

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On January 1, 2006, Medicare began offering voluntary prescription drug coverage to Medicare beneficiaries, including those who reside in a nursing home, through the Medicare Part D program. Part D, created by the Medicare Modernization, Improvement and Prescription Drug Act of 2003 (MMA), relies on private plans to administer the benefit.

The Part D drug benefit fundamentally altered the nursing home pharmacy market.<sup>1</sup> The most significant changes created by Part D center on the majority of nursing home residents who are dually eligible for Medicare and Medicaid (i.e., “duals”). The MMA shifted drug coverage for duals from Medicaid to Medicare, requiring the enrollment of duals in private Part D prescription drug plans (PDPs). Under Part D, nursing homes and the long-term care pharmacies (LTCPs) with which they contract no longer function primarily under a single state’s Medicaid policies but must instead work across multiple plans, each of which generally has different coverage, formulary design, and utilization management.

Part D includes special protections for nursing home residents, but its core administrative reliance on private plans and emphasis on consumer choice is the same across institutional and community settings even though beneficiaries residing in nursing homes differ from their community-based counterparts in important ways. Medicare beneficiaries living in nursing homes are typically frail, suffer disproportionately from multiple chronic conditions, have higher levels of cognitive impairment, and typically take six to ten different medications.<sup>2-4</sup> In addition, medications are dispensed through different mechanisms for nursing home residents relative to community-based beneficiaries, who are primarily served by retail pharmacies: most nursing facilities contract with a LTCP to provide a range of specialized pharmacy services to their residents, including alternative packaging, 24-hour access, specialized compounding, and emergency delivery.<sup>5</sup>

In 2006, the Medicare Payment Advisory Commission (MedPAC) contracted with Harvard Medical School to explore how the introduction of Part D had changed the operation of LTCs and nursing homes, as well as the implications of those changes for beneficiaries and the Medicare program. A report released in June 2007 summarized findings from a series of stakeholder interviews across a variety of relevant perspectives conducted between November 2006 and January 2007.<sup>1</sup> In 2009, MedPAC contracted with Harvard Medical School to update its 2007 report by conducting a second round of stakeholder interviews. This report summarizes our findings from these interviews.

### Project and Methods

As for the 2007 report, we interviewed stakeholders across a variety of relevant perspectives and reviewed existing sources of information. Unless otherwise noted, qualitative data collected from these interviews provide the basis for the information we present. A total of 24 semi-structured telephone interviews were conducted between November 2009 and January 2010. Stakeholder groups from which we collected information included nursing homes (n=8 interviews), LTCs (n=4), Part D plans (PDPs) (n=3), financial analysts covering the long-term care pharmacy sector (n=2), physicians working in nursing homes (n=1), consultant pharmacists (n=2), federal policymakers (n=1), and advocates for nursing home residents (n=3). In many instances, multiple individuals from the same organization participated in a given interview. Separate protocols were developed for each of the stakeholder groups, and interviews were generally 30-60 minutes in length. Selection of stakeholders sought to maximize representation among Medicare beneficiaries (e.g., efforts were made to interview the larger nursing home chains, LTCs, and PDPs). To examine whether and how perspectives and experience may differ

for smaller providers and pharmacies, interviews were also conducted with these types of provider organizations; however, the findings may be less representative of the range of experience across these smaller entities. In response to our request for a stakeholder interview, the American Society of Consultant Pharmacists (ASCP) fielded a survey of LTCP administrators and consultant pharmacists, and we have incorporated information reported in that unpublished survey where applicable.<sup>a</sup> In a written consent form distributed prior to each interview and reviewed verbally at each interview's start, interviewees were assured the information provided would not be identified with them individually or organizationally. The study design, protocols, and consent form were all approved by the Committee on Human Subjects at Harvard Medical School.

The report begins with a brief update on changes that have occurred in the LTCP industry since early 2007, integrating information provided by financial analysts as well as publicly-available information about the sector. The report goes on to describe the recent impact of Part D in the nursing home and LTCP sectors focusing on: Part D plan assignment and selection; PDP formularies and drug coverage; mechanics of dispensing medications to nursing home residents under Part D; and the impact of Part D on drug utilization and health outcomes for nursing home residents.

#### Update on the Long-term Care Pharmacy Industry

Our 2007 contractor report provided a general overview of the long-term care pharmacy (LTCP) industry at that time.<sup>1</sup> Below we provide an update to that earlier overview, focusing on changes that have occurred since March 2007.

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<sup>a</sup> 230 individuals responded to the ASCP survey. Approximately two-thirds of respondents reported that they were long-term care pharmacy administrators and a little over one-fifth reported that they were employed as consultant pharmacists. No overall response rate was available.

### *Market changes*

Over the past three years, there has been further consolidation in the LTCP sector. In July 2007, PharMerica and Kindred (the second and third largest LTCPs at the time) merged, keeping the PharMerica name. Two large pharmacies—Omnicare and PharMerica—now account for approximately three-quarters of the LTCP market. Omnicare serves approximately 1.4 million long-term care residents, including both nursing home and assisted living residents, while PharMerica serves approximately 315,000. Although precise estimates are not available,<sup>b</sup> Omnicare serves around 60% of the nation's 1.7 million nursing home beds, while PharMerica serves around 15%. Market shares for Omnicare and the merged PharMerica have remained relatively constant since Part D was implemented. The remainder of the industry consists of smaller local and regional LTCPs that may individually serve between 50-100,000 beds in an area. Many of these independent LTCPs join together as group purchasing organizations (GPOs) to contract with PDPs. The three largest GPOs are Gerimed, Managed Healthcare Associations (MHA), and Innovatix.

Industry analysts reported that LTCPs have worked to increase efficiencies over the past few years through consolidation and reorganization of administrative and production functions, redeployment of human capital, investments in new technologies, and efforts to better manage their inventories.<sup>c</sup> Analysts noted that prices LTCPs charge to nursing homes for their services, which recently have been a subject of scrutiny by the U.S. Department of Justice,<sup>d</sup> no longer

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<sup>b</sup> The LTCPs we interviewed did not provide information on the number of residents served by type of care long-term care services the individuals were receiving (e.g., number receiving skilled care vs. assisted living vs. hospice). LTCPs cited proprietary reasons for not divulging detailed data of this type.

<sup>c</sup> For example, one recent effort to increase efficiency undertaken by Omnicare is described in: <http://ir.omnicare.com/phoenix.zhtml?c=65516&p=irol-newsArticle&ID=888420&highlight>

<sup>d</sup> In November 2009, the Department of Justice (DOJ) announced that Omnicare care would pay \$98 million to resolve allegations that Omnicare paid kickbacks to nursing homes by providing consultant pharmacist services at rates below cost in order to induce the nursing homes to contract with Omnicare as well as other allegations that Omnicare had received kickbacks from Johnson & Johnson in exchange for agreeing to recommend that physicians



vary much across LTCs.<sup>6, 7</sup> LTCs now compete primarily over ways of offering better service to nursing home clients, in the form of items like electronic medical record technology, online refill capability, paperless claim entry, and frequency of medication deliveries. Analysts also noted that large LTCs have recently been trying to strengthen their capacity to address needs of nursing home residents such as large molecule (i.e., biologic) drug delivery systems and intravenous therapies. For example, in 2009, Omnicare acquired Advanced Care Scripts, expanding its capacity to dispense high-cost injectable and oral medications directly to patients.

#### Part D Plan Assignment and Selection

A central feature of the Medicare Part D benefit is its administrative reliance on private PDPs. Within limits, plans have flexibility to structure their formularies, cost-sharing, and other plan features, with the expectation that plans will compete on price and that informed consumers will select the plan that is best-suited to meet their individual needs. During annual open enrollment periods, Medicare beneficiaries select from the many stand-alone PDPs and Medicare Advantage plans that will offer drug coverage in their region during the upcoming calendar year. Like they do for other Medicare beneficiaries, private plans administer the Part D benefit for individuals who are dually eligible for Medicare and Medicaid (“duals”) and for those who are living in nursing homes; however, there are important differences in how these individuals enroll in plans. To ensure continuity of coverage and to mitigate the potential for adverse selection, duals are assigned randomly to PDPs with monthly premiums at or below regional benchmarks, and they can switch to a different plan at or below the benchmark up to once per month.

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prescribe Risperdal. Omnicare did not admit wrongdoing in these cases. In a separate action, the DOJ made similar allegations about kickbacks for pharmacy services contracts against Omnicare, Mariner Health Care, and SavaSenior Care; Mariner and Sava recently agreed to a \$14 million settlement in this case.

Although non-dual nursing home residents are not auto-enrolled, they may also switch plans up to once per month.

*Random assignment and steering.* In both the 2006/2007 interviews and the recent round of interviews, some stakeholders questioned the wisdom of randomly assigning nursing home residents to drug plans, reasoning that some residents inevitably will be enrolled in plans with relatively less generous coverage of the medications they are taking and may not change to a more advantageous plan. More broadly, some of these same stakeholders questioned Part D's emphasis on consumer choice of plans, arguing that the approach is a particularly poor fit for nursing home residents who may have cognitive impairments and may not have family members actively engaged in their medical decision-making and knowledgeable about their care.

Part D guidance restricts nursing home and long-term care pharmacy providers from directing or “steering” residents to particular plans. The policy is designed to mitigate potential conflicts of interest that might arise if nursing homes or pharmacies recommend enrollment in particular plans. Providers may provide objective information to residents, including information about how well particular PDPs cover their medications, but they are not permitted to steer residents to a subset of plans or to distribute information that could be construed as having this aim. Similar to sentiments expressed during our initial round of interviews, some nursing home administrators, resident advocates, and even one PDP stakeholder expressed the view that nursing home staff should be able to assist residents and family members in selecting a plan that best meets their medication needs, including making specific plan recommendations. The rationale for this position centered on the notion that the nursing home is the entity responsible for ensuring residents' care needs are met, that some residents and family members would like (and indeed expect) the nursing home to play this role, and that this could be a

superior mechanism to align plan choice with individuals' needs. At the same time, other nursing home providers continued to support the restrictions on steering of residents by LTCs and nursing homes, stating that such a role could pose a conflict of interest and open providers to the liability related to recommending particular plans. When asked about practices to educate residents' about their plan choices, nursing home and pharmacy providers reported practices ranging from resident-specific assessments of plan-by-plan coverage to the provision of general information about the relative restrictiveness or generosity of particular plans within a market. A similarly-focused 2008 Department of Health and Human Services Office of the Inspector General (HHS/OIG) study found that nursing home administrators and operations directors engage in a range of behaviors to assist their dual eligible residents in making plan choices.<sup>8</sup> Only about 8% of nursing home administrators and staff surveyed indicated that they or their LTCs steer most duals to a single plan or recommend one plan to each resident. About one-third said that they provided some information about plans to their residents and one-third said that they worked with residents to find a plan through the CMS Medicare Plan Finder.

Nursing home and pharmacy stakeholders posited that residents generally remain in the plans to which they are assigned and that facilities generally have residents enrolled in multiple plans within a facility. One recent conference presentation of preliminary analyses using 2006 and 2007 Medicare data estimated that close to one-quarter of all dual eligibles switched plans during that period, and institutionalized dual eligibles were more likely than community-based dual-eligibles to do so.<sup>9</sup> To date, there have been no analyses of plan switching at the facility- or chain-level, which could help shed light on the extent to which steering may be occurring.

*Plan reassignment.* Stakeholders of all types (nursing home, LTCs, PDPs, and others) reported problems associated with plan reassignment of duals from one calendar year to the next.

When a benchmark PDP's premium bid for the upcoming year exceeds the new benchmark rate, dual eligibles who had been randomly assigned to that plan will be reassigned automatically to a plan with a premium at or below the benchmark for the upcoming year. For example, approximately 3.3 million duals<sup>e</sup> were enrolled in plans that lost their benchmark status between 2009 and 2010.<sup>10</sup> Of the 409 benchmark plans available in 2006, only 23 percent of these plans were still available to LIS beneficiaries in 2009.<sup>11</sup> Automatic reassignment either occurs to another plan from the same company (e.g., moving from one Aetna plan to another), or – if there is no benchmark option from the same company in the same region – occurs via random assignment. Multiple stakeholders noted that plan reassignments are problematic and can lead to potential disruptions in medication regimens in addition to the administrative burden of this “churn” for nursing homes, LTCs, and physicians. To mitigate these challenges, the Centers for Medicare and Medicaid Services (CMS) has instituted safeguards for individuals who are newly enrolled in a PDP (including individuals reassigned at the beginning of the calendar year), requiring plans to cover all medications over a 90-day transition period for new enrollees who live in nursing home settings (see below for additional detail).

Benchmark plan exit creates additional complications for duals who were not initially randomized to an exiting plan but instead voluntarily chose that plan (sometimes referred to as “choosers”). When their plan's premium bid exceeds the regional benchmark, choosers may either select a different plan with a premium below the benchmark for the coming year or remain in their current plan and pay the difference between the premium and the benchmark rate. CMS does not automatically reassign choosers. Choosers and their family members or guardians are notified in writing of the issue before the new calendar year starts; yet, many of these individuals

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<sup>e</sup> Each year, a sizeable number of dual-eligible beneficiaries have been reassigned when their plan lost benchmark status for the coming year. CMS reassigned 1.1 million duals for 2007, 2.1 million for 2008, and 1.6 million for 2009.

reportedly do not choose a new plan and, thus, begin receiving bills for the premium difference in January. Nursing home representatives reported that they and their pharmacies typically learn of this type of situation either when family members begin receiving these bills and contact the facility or when prescription drug claims start to be rejected after individuals are disenrolled from plans for non-payment of the additional premium amounts. In either scenario, nursing homes and pharmacies immediately work with residents and their families to select a new benchmark plan; however, this enrollment does not take effect until the first day of the following month. In the context of this challenge, nursing home providers felt the issue could be handled more effectively if the facility were notified of the potential need for reassignment in the fall at the same time as families.

Stakeholders generally were attuned to a surfeit of plan choices and the related challenges of working across distinct plan formularies, and we did not hear of challenges related to having insufficient choice of plans at this time. However, a few stakeholders raised long-term concerns about benchmark plan availability. In 2010 there are 307 benchmark plans available—102 fewer plans than were available in 2006.<sup>12</sup> In some regions, benchmark plan choice is somewhat limited. For example, in 2009, duals residing in Nevada had only one benchmark plan option, although the number of plans serving the region increased to 5 in 2010.<sup>12</sup> One stakeholder pointed to the narrowing of the risk corridors over time as one reason why fewer plans now serve the dual-eligible market.

*PDP-LTCP Contracting.* When Part D was first implemented, a key concern was that the program could disrupt the one nursing home—one LTCF arrangement that most facilities had. By all accounts, this concern has not come to pass. However, in our most recent interviews, nursing home stakeholders expressed concern that contractual disputes around pricing (primarily

dispensing fees) between the larger LTCPs, which account for a sizable portion of the market, and PDPs could jeopardize these arrangements. In particular, for chain nursing home companies that use a single LTCP provider, contracts would have to be signed with other pharmacies if their primary LTCP vendor could not reach an agreement with a particular PDP.

### PDP Formularies and Drug Coverage

Medicare Part D PDPs maintain formularies for drug coverage, and these formularies vary across plans. Beyond coverage of particular medications, PDPs are permitted to use utilization management techniques, such as prior authorization requirements (i.e., requiring a physician to obtain prior approval for coverage of a particular medication), step therapy requirements (i.e., requiring documentation that a beneficiary has tried one or more lower-cost medications and not had an appropriate response before granting coverage of higher-cost medications that treat the same condition), and quantity limits (i.e., limiting the days supplied of a medication that will be covered within a given period of time), to control drug utilization. In our first round of interviews, stakeholders generally reported that coverage of most medications used commonly by Medicare beneficiaries living in nursing homes was adequate, although some stakeholders noted what they considered to be important exceptions.<sup>1</sup>

Similar assessments were shared during the most recent round of interviews, with stakeholders of different types indicating that coverage generally was adequate to meet most medication needs of nursing home residents. Yet, most nursing home and LTCP representatives also suggested that the use of utilization management requirements for drugs used commonly by this population had increased over the last few years, a trend that is consistent with findings presented to MedPAC in January 2010 about PDP formulary coverage more generally.<sup>13</sup> These stakeholders noted the additional administrative burden these processes can place on nursing

homes, LTCs and physicians and the potential for clinical disruptions these requirements may cause (described in more detail below). When asked about particular medications or classes where coverage was especially challenging, nursing home, LTC, and consultant pharmacist stakeholders noted difficulties in several areas, including Alzheimer's drugs, atypical antipsychotics, antidepressants, selected antibiotics, erythropoietin medications, sedative/hypnotic drugs, pain medications, angiotensin receptor blockers (ARBs), eye drops, insulins, nebulized inhalants, statins, and intravenous solutions. According to stakeholders who described these challenges, coverage restrictions may be based in clinically appropriate concerns (e.g., around prescribing of psychoactive drugs) and can arise for different reasons. For example, PDPs might cover the antidepressant Celexa and not Lexapro, with some nursing home clinicians with whom we spoke arguing the latter is more appropriate for individuals with Alzheimer's or anxiety. Similarly, PDPs might cover the generic warfarin sodium and not the brand name Coumadin, even though a nursing home medical director with whom we spoke expressed the perception that the former can contain impurities that make it dangerous to prescribe. Importantly, coverage issues can extend to dosage form, as obtaining liquid or rapidly dissolvable forms of some medications for individuals with feeding tubes or swallowing problems was described as challenging. One nursing home clinician described frustration at the potential tradeoff he saw between offering adequate coverage of a liquid medication form and nursing home staff (inappropriately) administering crushed medication into a gastrostomy tube, which may ultimately clog and lead to its necessary replacement. Nursing home clinicians also expressed frustration around quantity limits that may be appropriate in the community setting but that are challenging to work around in nursing homes. For example, some consultant

pharmacists reported that quantity limits can be problematic when a nursing home physician attempts to titrate a dose slowly over several days or weeks to stabilize the patient.

It is important to note, however, that utilization management requirements may provide important safeguards in cases where prescribing could be questionable or inappropriate, either due to controversy about efficacy or concerns about risks or side effects. For example, many nursing home stakeholders identified the erythropoiesis stimulating agents as a class of medications for which coverage issues were particularly challenging. In response to studies that found these medications may speed tumor growth and result in earlier death for some cancer patients, the Food and Drug Administration (FDA) issued a safety announcement about these medications in April 2008 that requires them to be prescribed through a risk evaluation and mitigation strategy (REMS) to ensure that all patients and providers are informed about the risks associated with their use.<sup>14</sup>

Stakeholder reports of increased use of utilization management are consistent with reports by the Kaiser Family Foundation and others that have documented greater formulary and utilization management restrictions as a whole in the Part D program since its creation. For example, a 2009 Kaiser Family Foundation report documented that the percent of prescription drugs subject to some utilization management restrictions, such as step therapy, prior authorizations and quantity limits, increased from 18 percent in 2007 to 28 percent in 2009.<sup>15</sup> In a 2008 report by the DHHS Office of the Inspector General, one-fifth of nursing home administrators interviewed reported concern that PDP formularies may not meet all needs of some dual-eligible residents.<sup>16</sup>



*CMS formulary safeguards.* Several policies have been implemented by CMS to help protect nursing home residents from PDP formulary limits.<sup>f</sup> First, CMS regulations currently require that PDPs cover “all or substantially all” medications in six medication classes, many of which are used commonly among nursing home residents: anticonvulsants, antidepressants, anticancer drugs, antipsychotics, immunosuppressants and HIV/AIDS drugs. Under this rule, PDPs must cover at least one formulation of every molecule in the class.<sup>g</sup> As noted above, though, PDPs are not restricted in the extent to which they may use prior authorization requirements, step therapy requirements, or quantity limits for these medications. Second, as noted above, PDPs are required to cover a 90-day supply of nonformulary drugs and drugs requiring prior authorization or step therapy for new PDP enrollees who reside in a nursing home, including enrollees who are reassigned in the context of their plan losing its benchmark status. Third, CMS requires that PDPs cover a one-time temporary or emergency supply (one prescription fill or up to a 31 day supply) of non-formulary Part D medications for long-term care residents to ensure that residents do not experience a gap in coverage while an exception or appeal request is being adjudicated for a drug requiring prior authorization or step therapy (<http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/CY07transitionguidance.pdf>).

One nursing home physician emphasized the importance of this particular policy in ensuring timely access to medications, noting that it can address an acute or emerging need quickly and even help avoid unnecessary hospitalizations of residents in some instances. More broadly, a few nursing home stakeholders emphasized the responsiveness of CMS to concerns that arise in

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<sup>f</sup> Importantly, CMS is considering regulatory changes that would affect the process by which it establishes protected classes in the future and other related protections (e.g., for comments on these proposed change, see <http://www.ascp.com/advocacy/upload/120809%20ASCP%20Comments%20on%20Policy%20changes%20and%20Clarifications.pdf>; <http://www.thenationalcouncil.org/galleries/policy-file/Comments%20on%20CMS%204085%20P%2012-7-09.pdf>).

<sup>g</sup> However, recent legislation codifying the requirement that PDPs must list “all or substantially all” drugs in these six classes allows CMS to establish exceptions that permit PDPs to either exclude a drug in the protected classes from its formulary or impose utilization restrictions (<http://edocket.access.gpo.gov/2009/pdf/E9-783.pdf>).

the context of the Part D benefit; however, these same stakeholders also noted that assistance often is on an ad-hoc basis and that more systematic solutions to problems might be more effective. One related request of these providers was that CMS Part D guidance be clearly dated and organized on the CMS website.

*LTCP formularies.* Before the implementation of Part D, LTCPs typically maintained their own formularies and received rebates from pharmaceutical manufacturers based on the volume of prescriptions filled for nursing home residents served by the LTCP. Importantly, these rebate arrangements have been criticized for putting financial considerations ahead of what is best for residents clinically.<sup>h, 6</sup> Given that PDPs have responsibility for maintaining formularies that govern Part D coverage for enrollees, it was initially unclear whether LTCPs would continue to maintain their own formularies for Part D covered residents. Different types of stakeholders reported that LTCPs continue to maintain formularies, although they reportedly are used primarily to guide prescribing for residents on skilled nursing facility (SNF) stays funded by Medicare Part A rather than prescribing for medications funded under Part D. For these Part A SNF stays, nursing homes receive a prospective payment that covers all post-acute services provided by the facility including all medications dispensed to residents during their stays. For these residents, the nursing home purchases medications directly from the LTCP.

Stakeholders generally expressed the view that LTCPs likely still receive rebates from pharmaceutical manufacturers, although most reported a belief that the magnitude of these rebates had decreased after the implementation of Part D. Starting in January 2007, LTCPs were required to report these rebates to the PDPs with which they contracted, who then passed this

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<sup>h</sup> As noted above, in November 2009, the DOJ announced that Omnicare would pay \$98 million to resolve allegations that it had solicited and received kickbacks from Johnson & Johnson in exchange for agreeing to recommend that physicians prescribe Risperdal to nursing home residents served by the pharmacy as well as other unrelated allegations.

information on to CMS. However, CMS suspended the collection of these data beginning in CY2008, stating that these data were not the most effective tools for ensuring “that Part D sponsors receive information necessary to effectively monitor LTC rebates to ensure that there are no associated inappropriate impacts on formulary drug utilization.”<sup>17</sup>

### Mechanics of Dispensing Medications to Nursing Home Residents under Part D

As described in our previous report, nursing home prescribing depends on a series of communications between several parties, including the prescribing physician, the nursing home, the pharmacy, and – now – the PDP. In our previous interviews, nursing home clinical staff noted several challenges that arose in the context of Part D, including making coverage determinations at the point of prescribing, receiving communication updates on PDP-physician interactions (e.g., around prior authorizations and appeals), and facing limitations in the parties that may contact PDPs on a resident’s behalf (e.g., some PDPs allowed nurses and pharmacies to play this role while others limited these interactions to physicians). Although nursing homes and their LTCPs have grown more accustomed to addressing these challenges over the course of Part D, these challenges largely remain in working across PDPs.

*Working across PDP coverage limits.* Few stakeholders shared experience with the appeals and exceptions process but rather focused more heavily on navigating prior authorization processes and meeting resident needs despite potential gaps in PDP coverage. Nursing home and LTCP stakeholders again reported that prior authorization and other utilization management requirements can be particularly challenging in the long-term care setting because of characteristics of nursing home organization and staffing. When a medication claim is denied by a PDP, the physician plays a central role in completing utilization management paperwork,

shepherding the appeals and exceptions process for the resident, or considering an appropriate therapeutic alternative for the resident. Importantly, nursing home physicians often practice primarily off-site and nursing home residents may represent a relatively small proportion of their practice. Many of these clinicians will not have residents' medical records at their primary practice sites, potentially making these processes more difficult. Nursing home, LTCP, and physician stakeholders expressed varying levels of success and frustration in getting medications claims approved by PDPs. One nursing home physician reported that he was "99% successful" in getting past prior authorization requirements and other claims hurdles, a success he felt was due both to his conservative prescribing approach overall and to his concrete explanations of the risks certain coverage limitations could pose to his patients. Others indicated much higher rejection rates, for example, indicating that almost 25% of claims requiring prior approval would be rejected even with what they considered to be proper documentation.

Stakeholders reported that some PDPs allow pharmacists to sign prior authorization forms to expedite this process, but many do not. Similarly, unlike in the retail setting, LTCPs, are usually relied upon by beneficiaries and nursing homes to initiate appeals for drug coverage and inquiries about claim status; yet, PDPs do not have to recognize LTCPs as agents of beneficiaries unless LTCPs have been officially appointed by the beneficiary to act on their behalf. Beneficiaries are able to fill out a form to make this designation but this form is rarely completed, reflecting the challenges of cognitively impaired residents and potentially distant family members. In the ASCP administered survey mentioned above, many LTCP administrators and consultant pharmacists requested that pharmacies routinely be permitted to initiate the prior authorization process on behalf of the physician and patient and that pharmacies

be informed about coverage or prior authorization determinations at the same time as physicians (many plans inform only physicians when these decisions are resolved).

In an effort to streamline the administrative processes used across plans and to reduce administrative burden for LTCPs and nursing home staff, CMS developed a model coverage determination request form for requesting a formulary exception or prior authorization approval and requires that all plans accept this form.<sup>18</sup> Nonetheless, LTCP stakeholders with whom we spoke reported that plans often require their own coverage determination form to be completed as well. In the absence of standardized utilization management forms, plans may have disparate information requirements for these requests, further impeding physicians' ability to address these requirements in an effective manner. One nursing home stakeholder also commented that some requirements can be inappropriate or especially burdensome in the context of nursing home residents, for example requiring endoscopy results for coverage of particular proton-pump inhibitors or extensive lab results for coverage of erythropoiesis stimulating agents. As noted above, these requirements may also add valuable safeguards to protect nursing home residents from potential harms of inappropriate prescribing in some cases.

As noted above, stakeholders agreed about the importance of CMS's transition and emergency fill policies in ensuring medication access for residents. However, nursing home and LTCP representatives also identified limitations with these policies with respect to addressing potential formulary inadequacies. For example, nursing home providers in particular expressed frustration that the initial prescription for a drug might be covered as an emergency or transition fill but that the need to obtain prior approval for the *next* dose or even to work with the clinician to identify an alternate therapeutic agent was often not known until the subsequent claim was rejected. A related point is that nursing home and LTCP providers expressed the view that the

policy hampered their ability to manage clinical risk in initially prescribing shorter dispensing cycles than 31 days. For example, physicians sometimes initially write a prescription for a duration shorter than 31 days for clinical reasons, such as the desire to titrate the dose of a new medication slowly. However, under the emergency fill policy, PDPs would not be required to cover a full 31 days of medication in this case – only the initial prescription. Accordingly, some nursing home and LTCP stakeholders suggested that the policy should be changed such that PDPs cover a 31 day supply regardless of the number of fills.

A broader point related to working across PDP requirements is that facilities, LTCPs, and clinicians must now work across formularies and policies of several plans within a facility (e.g., in contrast to Medicaid). Several non-PDP stakeholders suggested the approach conflicted with a trait they valued most in the context of nursing home prescribing – consistency. One nursing home representative noted that even though Medicaid coverage could be challenging in particular states prior to Part D, everyone involved recognized these limitations well and worked around them. Although nursing homes, LTCPs, and clinicians are gaining experience with how to navigate effectively across plans (e.g., one physician mentioned prescribing medications that typically have broad coverage across multiple plans), the notion that Part D’s multi-plan approach was a poor fit for the nursing home setting came up repeatedly. For example, one nursing home representative expressed the view that all benchmark plans should be required to provide a baseline of coverage that represents an acceptable floor for nursing home residents. A PDP representative recommended reforms that would go even further, for example creating a single national formulary for all nursing home residents or establishing a single plan for nursing home residents in each region and allowing PDPs to bid competitively to offer such a plan. These types of approach would also mitigate the plan transition issues mentioned above.

*Financial and administrative challenges of working across PDPs.* Compared to the retail pharmacy setting, several administrative and financial challenges arise in the context of Part D in nursing homes. First, medications generally are dispensed to residents prior to payment being assured. Nursing home, LTCF, and clinical stakeholders pointed to regulatory requirements for timely medication delivery to nursing home residents (e.g., within four hours from the time the prescription is received) as generally being too short to complete the necessary administrative processes required by PDPs. In interviews, both LTCFs and nursing homes were particularly attuned to the financial burden of non-covered medications. The reasons for non-coverage can range from drugs not being on a plan formulary to unmet utilization management requirements, such as hitting quantity limits or not getting prior authorization. Nursing home stakeholders reported that these costs are considerably higher than they were prior to Medicare Part D and are continuing to increase. In a DHHS OIG study, 45% of nursing home administrators reported that their facilities paid for at least one Part D drug for dual-eligible residents.<sup>16</sup> Arrangements of financial risk between LTCFs and nursing homes are somewhat sensitive and subject to negotiation, and stakeholders declined to provide specific details. Still, nursing home and LTCF representatives generally indicated that nursing homes typically assume ultimate financial responsibility for non-covered drugs. Thus far, both nursing homes and LTCFs indicated that medication access for residents has not suffered, while also wondering whether this would change in the context of possible SNF reimbursement cuts in the future (e.g., in its March 2010 report,<sup>19</sup> MedPAC concluded that SNF payments were sufficient to accommodate any potential cost growth and recommended that Congress eliminate the update to payment rates for skilled nursing facility services for fiscal year 2011). Nursing homes and LTCFs shared information about various processes used to minimize financial risk and increase mutual trust that both sides

are doing due diligence to get the charges reimbursed. One such process is shortened-cycle dispensing, which means filling prescriptions for five or seven days rather than the more typical thirty one day period, although this strategy can face challenges in the context of CMS's emergency fill policy mentioned above. Of note, one of the potential policy changes discussed under health reform is to reduce waste in prescription medications by standardizing shorter cycles for all Part D prescriptions to long-term care residents.<sup>20</sup>

A financial issue that continues to bedevil Part D stakeholders in the context of nursing homes pertains to beneficiary co-payments inappropriately being withheld from medication payments for duals who reside in nursing homes. In particular, despite stakeholder reports that the magnitude has declined relative to 2006 and 2007 levels, some difficulties remain in being able to identify reliably when individuals are (a) full benefit duals and (b) nursing home residents. LTCPs do not charge co-payments to duals living in the nursing home, but they may not be reimbursed for these co-payments if state computer systems do not correctly categorize residents as LIS-eligible. The financial implication of this gap means losing between \$2.50 and \$6.30 per prescription (depending on whether brand or generic). Some LTCPs and consultant pharmacists reported that the system has improved somewhat because of better identification of LIS patients by states and by CMS and because of improved administrative systems of the larger PDPs. Another reported factor in these improvements is the change in CMS policy to indicate that LTCPs should be reimbursed if they can provide "Best Available Evidence" (BAE) that the resident is eligible for LIS. Still, LTCP and consultant pharmacist stakeholders reported that the collection of BAE information can be "cumbersome" and time consuming and that BAE information often needs to be submitted multiple times before the co-payment is reimbursed. One LTCP representative reported a decrease in the amount of copayments the pharmacy had



written off as uncollectable since the BAE rules were implemented, although the pharmacy attributed the decrease primarily to increased labor resources devoted to gathering BAE information over time and to changes in payment practices made by PDPs in response to the threat of litigation by LTCPs.<sup>21</sup>

A final area where LTCPs are distinct from retail pharmacy settings pertains to dispensing requirements. Like retail pharmacies, LTCPs receive a dispensing fee for each prescription they fill but representatives report that these fees are inadequate to cover their costs of doing business. LTCP argue that their dispensing costs are higher than in the retail and mail order settings for several reasons related to relevant regulatory requirements, such as unit-dose packaging, 24-hour drug delivery, emergency drug supplies, and handling unused medications. A recent study commissioned by MedPAC and conducted by Acumen, LLC found that dispensing fees for institutional beneficiaries are higher than dispensing fees for community beneficiaries.<sup>22</sup> For example, Acumen, LLC reported that dispensing fees add approximately 12% to median drug prices for institutional beneficiaries over the period 2006-2008 vs. approximately 4-5% for community-residing beneficiaries. A previous HHS/OIG study comparing Part D and Medicaid dispensing fees to local, community pharmacies found that Part D dispensing fees were, on average, two dollars lower than Medicaid dispensing fees.<sup>23</sup> When asked about dispensing fees paid to LTCPs relative to retail pharmacies, PDP representatives stated that they generally have the upper hand in negotiations with LTCPs, which represent a small portion of their business, although minimum pharmacy access requirements may limit PDP negotiating power to some extent with the larger LTCPs.

## Impact of Part D on Drug Utilization and Health Outcomes for Nursing Home Residents

Assessing the clinical impact of Part D in the nursing home sector is one of the more difficult areas to evaluate without empirical data describing drug utilization and other related processes and outcomes for nursing home residents. With this caveat, nursing home and LTCP stakeholders generally posited that – outside of an industry-wide trend toward generics – overall utilization of drugs by nursing home residents had not changed during the course of Part D. As mentioned above, nursing home and LTCP stakeholders further reported that residents generally receive medications in a timely fashion regardless of PDP coverage rules. This finding from our stakeholder interviews was generally consistent with our previous interviews and with a 2008 DHHS Office of the Inspector General Report finding that 93% of nursing home administrators reported that dual-eligible residents were receiving all necessary Part D drugs.<sup>16</sup> Federal regulations require that nursing homes provide all medications included in a resident's care plan, regardless of coverage for services. As a result, prescriptions are filled by the LTCP and then – if the drug remains uncovered – either the nursing home or the LTCP must cover the cost of the medication. One nursing home representative noted that, despite the administrative hurdles, as long as prescribing physicians are cooperative, medication needs for residents can be addressed.

An initial concern about Medicare Part D was that nursing home residents, particularly dual-eligible residents transitioning from Medicaid coverage to a Medicare PDP, might experience adverse health outcomes due to disruption of medication regimens or PDP limits on coverage of medications used commonly in this population. To date, there is only very limited empirical evidence on the impact of Part D on health outcomes or quality of care for this population. A recent study by Briesacher and colleagues using LTCP dispensing records on nursing home residents found that implementation of the Part D program in 2006 was associated

with a temporary but statistically significant decrease in average monthly prescription use per resident of about half a prescription.<sup>24</sup> This study did not, however, examine medication switches or discontinuations resulting from Part D, the impact of Part D on resident health or functional outcomes, or the effects of Part D on utilization beyond the first year of the program. A CMS analysis conducted by Acumen, LLC examined 2007 Medicare claims to assess whether beneficiaries who were reassigned to a new PDP for 2007 (after their 2006 PDP exited the low-income subsidy market) experienced adverse health outcomes relative to beneficiaries who remained in their 2006 PDP and were not reassigned for 2007.<sup>25</sup> Using multivariate regression techniques to adjust for differences in demographic characteristics and health histories (i.e., the RxHCC risk adjustment variables), these analyses found no statistically significant difference in mortality, hospital admissions, or emergency room visits between the two groups. Subanalyses of institutionalized beneficiaries reached similar conclusions. This study did not document the extent of medication changes or discontinuations after plan reassignment or the impact of Part D on health and functional outcomes besides mortality, however. The study also did not assess the impact of Part D plan generosity on utilization or health outcomes for nursing home residents.

More generally, advocates, physicians, LTCs, and nursing home representatives did not perceive there to be major adverse health problems associated with Medicare Part D for nursing home residents, potentially because residents typically receive their medications regardless of whether pharmacies or facilities ultimately are reimbursed. Some stakeholders did raise the concern that people are being switched to new medications for non-health reasons (e.g., because of plan and/or formulary changes), possibly increasing the potential for medication errors and other problems related to these switches. Several stakeholders noted that an empirical

assessment was necessary to accurately estimate the impact of Part D on long term care resident health and drug utilization.

Medication therapy management (MTM) programs are one tool used by the Part D program with a goal of reducing adverse drug events and improving medication therapy quality. PDPs are required to sponsor MTM programs, which must include an annual comprehensive medication review and no less than quarterly targeted medication reviews, for beneficiaries in three targeted groups: 1) individuals with multiple chronic conditions, 2) individuals taking multiple medications, and 3) individuals expected to incur annual costs for Part D covered drugs that exceed a predetermined threshold (initially, \$4000).<sup>26, 27</sup> We heard little from stakeholders interviewed about the use of MTM programs for institutionalized beneficiaries. One PBM stakeholder reported that although some PDPs have extended MTM to long-term care residents, MTM had not been a focus for nursing home residents in part because of the overlapping federal requirement for monthly drug regimen review by a consultant pharmacist for nursing home residents. The stakeholder noted that the recent drop in the threshold for the third targeted group above from \$4000 to \$3000 may result in more nursing home residents receiving MTM services in the future.

## Conclusions

Since our initial report, stakeholders of all types have gained experience working through issues related to Part D coverage for nursing home residents. In the context of this increased experience and related safeguards adopted by CMS, many of the initial implementation challenges that arose during the transition to Part D have lessened over time. Overall, it seems providers have adapted to the new benefit and learned to work around its limitations. In general,

Part D does not appear to be a front burner issue for nursing home providers (e.g., relative to payment concerns), and resident advocates have not heard about substantial problems for nursing home residents in obtaining needed medications. Nonetheless, most stakeholders continued to describe the Part D program, particularly its reliance on multiple private plans to administer the benefit and its emphasis on consumer choice, as a poor fit for the nursing home setting, while at the same time warning of important challenges that remain. In sum, our stakeholder interviews provided the following central insights:

- The LTCF industry remains competitive, and LTCFs have worked to increase efficiency and lower costs over the past several years. Analysts noted that prices LTCFs charge nursing homes for LTCF services are now similar across pharmacies, with LTCFs competing primarily on services delivered to nursing home clients. Consolidation over the past several years has resulted in a market dominated by two large companies (Omnicare and PharMerica), although smaller and medium-sized pharmacies (often organized through GPOs) play an important role in the market as well. Pharmaceutical manufacturers continue to pay LTCFs rebates based on their volume of prescriptions, although stakeholders reported that these rebates had diminished in magnitude since Part D was implemented.
- A tension between allowing residents and their family members the freedom to choose a drug plan and allowing nursing home providers to encourage enrollment in particular plans persists. Both nursing home providers and resident advocacy organizations requested that nursing home providers be permitted to play a greater role in educating residents and family members about plan differences.

- Formulary coverage is still generally viewed as adequate for meeting the needs of nursing home residents in most cases, although stakeholders again noted what they consider to be important exceptions to overall formulary adequacy for the institutionalized population. Stakeholders also noted that the use of utilization management requirements such as prior authorization, step therapy, and quantity limits had increased over the past few years, a trend consistent with previous MedPAC-supported research on Part D formularies generally. CMS-instituted safeguards have reportedly helped lessen potential disruption to residents; however, important limitations to these safeguards were expressed (e.g., PDPs may cover a limited prescription fill rather than a 31 day supply if physicians initially fill a shorter duration prescription for clinical reasons). Stakeholders also noted that some PDPs allow the pharmacy to sign prior authorization forms, which reduces the administrative hurdles for nursing homes and LTCs; however, most PDPs do not allow this. Nursing home stakeholders pointed to continued discrepancies in the information needed to satisfy utilization management requirements across plans and requested greater standardization in these policies.
- Annual reassignment of dually eligible beneficiaries whose plan loses its benchmark status for the coming year results in significant disruption and administrative burden for residents, nursing home providers, and LTCs. The 90-day transition policy instituted by CMS helps to lessen the disruption and allow time for changes in medication regimens to be made. Yet, several stakeholders of different types described the “churning” of residents across plans from year to year as the biggest challenge associated with Part D at this time. Plan exit from the dual eligible market due to loss of benchmark status may be particularly difficult to negotiate for individuals who voluntarily selected one of these

plans (as opposed to being auto-assigned to it). Nursing home and advocacy stakeholders reported that these “choosers” are often uncertain about how to respond to notifications about the loss of benchmark status for their plan, and nursing home providers are not able to assist them in a timely manner because they are not notified about it directly.

- The number of benchmark plans serving dual eligibles decreased by 25% from 2006 to 2010, with some regions having few benchmark plan options in a given year. Although some stakeholders raised concerns about the future availability of benchmark plan options for duals given this trend, others focused more on the confusing number of plan options for residents at this time and the challenges facilities face in working across these plans.
- Stakeholders have not perceived a change in overall drug utilization after Part D’s implementation nor any adverse impact on resident outcomes or quality of care attributable to Part D. Yet, stakeholders agreed that empirical analyses are needed to assess the impact of Part D on utilization, health and functional outcomes, and quality.
- Due to regulatory requirements for timely medication dispensing for nursing home residents, LTCs must often dispense medications before payment is assured by the plan. Because nursing homes are required to provide timely access to all medications in a resident’s care plan regardless of whether a PDP covers a drug or has particular utilization management procedures in place (e.g., prior authorization or step therapy), nursing homes and/or the LTCs with which they contract must absorb the costs of uncovered medications. Nursing home stakeholders reported that these costs are considerably higher than they were prior to Part D, are continuing to increase over time, and remain a source of tension between nursing homes and LTCs.

- Nursing home providers, LTCPs, and consultant pharmacists also reported continued concerns about the process for identifying dual-eligible nursing home residents and difficulties in securing reimbursement for copayments withheld before dual eligibility is recognized by the PDP. Stakeholders generally noted some improvement since CMS adopted the “Best Available Evidence” (BAE) guidance, while at the same time noting complexities in these criteria and continued difficulty in obtaining timely reimbursement.
- Communication between nursing homes, physicians, pharmacies, and PDPs around nursing home prescribing remains tenuous in the context of Part D. A complicating factor mentioned by LTCP and nursing home stakeholders is that they often are not included in key communications about plan assignment and coverage decisions for residents (e.g., around the need for some residents to select a new benchmark plan or the resolution status of prior authorization or other utilization management policies).



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